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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,563	07/08/2005	Eva Steiness	50412/020003	2651
21559	7590	12/18/2009	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			EWOLDT, GERALD R	
			ART UNIT	PAPER NUMBER
			1644	
			NOTIFICATION DATE	DELIVERY MODE
			12/18/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No. 10/517,563	Applicant(s) STEINESS, EVA	
	Examiner G. R. Ewoldt, Ph.D.	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 24-39 is/are pending in the application.
- 4a) Of the above claim(s) 31-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22, 24-30 and 36-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/9/05</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1644

DETAILED ACTION

1. Applicant's election with traverse of the GLP-1 related molecule: COMPOUND 1 (SEQ ID NO:5), filed 12/10/07, is acknowledged. Applicant's additional election without traverse of the additional anti-diabetic drug: Lys(B28)Pro(B29) human insulin, filed 9/10/09, is also acknowledged.

2. Applicant argues that it would not present an undue burden to search additional species.

As set forth in the Restriction Requirement examination of the additional species would require search, examination, and considerations that comprise undue burden. Accordingly, restriction is proper and the requirement is made FINAL.

3. Claims 31-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected species.

Claims 1-22, 24-30, and 36-39 are under examination.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-22, 24-30, and 36-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically:

A) In Claim 1, "GLP-1 effect" is vague and indefinite as the specification fails to define said effect. It is unclear whether the term encompasses "effects" that would be unrelated to the treatment of diabetes, e.g., as an antigen.

B) In Claims 11 and 12, the term "mammal bolus" is vague and indefinite as it is unknown in the art.

C) In Claim 39, diabetes "associated" with a genetic disorder is vague and indefinite as it is unclear what being "associated" with a genetic disorder encompasses.

Art Unit: 1644

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-22, 24-30, and 36-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Under *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession* of the invention, and that the invention, in that context, is whatever is now claimed.

There is insufficient written description to show that Applicant was in possession of:

- A) A GLP-1 related molecule having GLP-1 effect (Claim 1).
- B) An exendin-4 analog or derivative (Claim 22).
- C) An insulin analog (Claim 28).

Regarding the GLP-1 related molecule having GLP-1 effect, said molecule is described by function, that is, a "GLP-1 effect", but no common structure is disclosed. Even regarding the "effect" limitation, said "effect" is not disclosed and is itself the source of a rejection under the second paragraph of 35 U.S.C. 112. The specification discloses that said molecules encompass derivatives, homologues, variants, and analogs (page 10), thus, it is clear that the genus is large and varied. While the specification discloses a list of said GLP-1 related molecules (spanning pages 17 and 18), said list comprises only closely related peptides, e.g., exendin-4 is 97% identical to GLP-1, thus, the disclosed species of said GLP-1 related molecules are not representative of the entire genus. Accordingly, one of skill in the art would conclude that the specification fails to disclose a representative number of species to describe the GLP-1 related molecule genus of the claims.

Art Unit: 1644

Regarding the exendin-4 analogs or derivatives, and insulin analogs of the claims, they are not described by structure or function, and few species are disclosed. Clearly, one of skill in the art would conclude that the specification fails to adequately describe these molecules. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-22, 24-30, and 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 91/04156 (IDS) in view of Roach et al. (1999).

WO 91/04156 teaches the administration of des Pro³⁶-exendin4(1-39)-Lys₆-NH₂ (COMPOUND 1) (SEQ ID NO:5 in the instant application, SEQ ID NO:101 in the reference) for the treatment of diabetes (see particularly Claims 22 and 35 and page 16).

The reference teaching differs from the claimed invention only in that it does not teach the further administration of Lys(B28)Pro(B29) human insulin in the claimed method.

Roach et al. teach the administration of Lispro (Lys(B28)Pro(B29) human insulin) for the treatment of diabetes (see particularly the Abstract).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform a method of treating diabetes, as taught by WO 98/58669, further comprising the administration of Lispro, as taught by Roach et al. One of ordinary skill in the art at the time of the invention would have been motivated to combine the treatments and administer both for the induction of an improved and longer-lasting response. The combining of known equivalents, in this case drugs for the treatment of diabetes, for the same purpose, in this case the lowering of blood glucose of the improved stimulation of insulin release, has long been held obvious, see *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069 (CCPA 1980).

Art Unit: 1644

Note that the limitations of the dependent claims comprise only routine optimization and fall well within the purview of the ordinarily skilled artisan.

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-22, 24-30, and 36-39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-8 of U.S. Application No. 12/277,148. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '148 application recite the treatment of diabetes with COMPOUND 1 (Claim 4) and an additional anti-diabetic human insulin analog (Claim 8) of which Lispro is an obvious well-known choice.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's

Art Unit: 1644

voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on (571) 272-0841.

14. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.

/G.R. Ewoldt/
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